

REMARKS

I. Overview

Applicants have reviewed and considered the Office Action dated April 4, 2006 and the references cited therewith. Claims 1-29 are pending in the instant application. Claims 6-7 and 13-21 have been canceled. New claims 30-37 have been added to more fully describe Applicants' invention. Support for these additional claims can be found in the original claims at page 35 lines 24-25 in the published specification and in the original claims as filed. In view of the amendments above and the remarks that follow, Applicants respectfully request reconsideration of the above-identified application. Applicants acknowledge the election of SEQ ID NO:2 in conjunction with the elected Group IV claims.

II. Specification

A. The legend of Figure 13 is objected to because it does not describe "related to amino acids". The Examiner writes the brief description on the figure should be amended to indicate that the figure represents degeneracy of genetic code.

Accordingly, Applicants have amended the legend of Figure 13 so that it now recites "Figure 13 shows an amino acid code table in terms of degeneracy of the genetic code."

B. The Examiner writes that the Abstract of the disclosure is objected to because of the following alleged informalities: Line 6 of the Abstract recites "significant wall-loosening agent". The Examiner suggests inserting --cell-- before "wall-loosening".

Applicants thank the Examiner for this suggestion and accordingly have adopted the language so the Abstract now recites "a significant cell wall-loosening agent".

III. Claim Rejections - 35 U.S.C. § 112

Claims 6, 7 and 14-21 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regard as the invention.

A. The Examiner writes that claims 6 and 7 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in their recitation "a group 2/3 allergen encoding a polypeptide", which is confusing, since it is unclear how an allergen can encode a polypeptide.

Applicants have canceled claims 6 and 7 rendering this rejection moot.

B. Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in its recitation "a carboxy terminus", which the Examiner writes is confusing, since it is unclear whether the polypeptide has more than one carboxy terminus. The Examiner writes further what defines the carboxy terminus, whether it is the last 5 amino acids, the entire C-terminal half of the amino acid sequence or what?

Applicants have canceled claim 21 rendering this rejection moot.

C. Claims 6, 7 and 14-21 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in its recitation "allergen", since it is unclear what the "allergen" comprises besides a polypeptide.

Applicants have canceled claims 6-7 and 13-21 rendering this rejection moot. As applied to claims 30-37, Applicants respectfully submit that claims 30-37 are definite as written. One skilled in the art reviewing the Specification, would understand the meaning of this term as used in the claims. The term "allergen" as recited in claims 30-37 is, as of Applicants' priority date, a

recognized term of art. See Ansari article (1989) cited by the Examiner. The Examiner is also referred to the instant Published Specification, in particular, paragraphs 3 and 12. In this context, Applicants' have employed this term in a manner consistent with its generally accepted meaning. Thus, the term conveys the nature of the invention with clarity to the reader so that one reading the Specification would know that the term refers to a polypeptide. Therefore, the rejection should be withdrawn. In the event that the Examiner maintains the rejection, Applicants would welcome discussions with the Examiner regarding alternative acceptable terms that are synonymous with this term that is equally defined by the disclosure.

IV. Claim Rejections - 35 U.S.C. § 101

Claims 20 and 21 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. Claims 20 and 21 allegedly read on a group 2/3 allergen per se, which is found in nature and thus, is unpatentable to the Applicant.

Applicants have canceled claims 20 and 21 rendering this rejection moot.

V. Claim Rejections - 35 U.S.C. § 112

A. Enablement

Claims 13-21 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated group 2/3 allergen from grass pollen encoding a polypeptide as defined in SEQ ID NO:2, allegedly does not provide enablement for any other group 2/3 allergen. Claims 13 and 14 allegedly encompass any group 2/3 grass pollen allergen having expansin activity and claims 15-22 allegedly encompass any group 2/3 allergen having

expansin activity and the ability to enhance the wall-loosening activity of a β -expansin in plant wall extension and stress relaxation activity.

As an initial matter, claims 6-7 and 13-21 have been canceled. Applicants respectfully submit that the basis for this rejection does not apply to new claims 30-37. Newly added claims 30-37 are directed to a protein preparation useful for the expansion of plant cell walls comprising a group 2/3 pollen allergen. Support for these amendments can be found throughout the specification as filed but particularly in original claims 6-7 and 13-21 and at page 35 lines 24-25 in the application as filed.

The Examiner writes that the claims 6-7 and 13-21 encompass a group 2/3 allergen protein that may have similar structural characteristics; however, Keskin et al. teach that proteins with similar structure may have different functions. The Examiner writes that, Thornton et al. teach that structural data may carry information about the biochemical function of the protein. The Examiner writes its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions.

One of skill in the art would be able to make and use the present invention without undue experimentation using well-known techniques available prior to the priority filing date of the present application. It should be noted that "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." MPEP § 2164.04.

Furthermore, "it is incumbent upon the Patent Office ... to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." MPEP § 2164.04. The rejection fails to satisfy this standard as it has provided no substantial reason to doubt the objective truth of the statements made by Applicants in its Specification as to the scope of the invention.

Enablement does not require that all encompassed embodiments be operative but rather that one skilled in the art can identify operative embodiments without engaging in undue experimentation. MPEP § 2164.06. "The test is not merely quantitative, since a considerable amount of experimentation is possible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." (In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988)). Moreover, the arguments raised in the Office Action do not refute Applicants' position that those skilled in the art are capable of identifying group 2/3 allergens having β -expansin activity with a reasonable expectation of success.

Indeed, as shown in Example 5 of the application, Applicants have identified and isolated a group 2/3 allergen from ryegrass pollen and a group 2/3 allergen-like gene from wheat ovary. Published Specification, at paragraph 12. This is in direct contrast to the Examiner's statement that the specification provides no guidance on the isolation and expansin activity associated with large numbers of group 2/3 allergens from pollen or other tissues as encompassed by the claims.

Applicants' specification provides ample guidance to the skilled artisan seeking to confirm whether a polypeptide is a group 2/3 allergen having β -expansin activity. As stated above, Applicants have demonstrated that group 2/3 allergens are not limited to a single

organism or species. Furthermore, the specification teaches the use of standard techniques for the isolation and purification of group 2/3 allergens. Published Specification, Paragraphs 12, 24, 94, and 129. The published specification, at paragraphs 47-48 and 75 teach the use of synthetic sequences as well as recombinants or variants of group 2/3 allergens for use with the present invention, including the cloning of such sequences into vectors and host cells. Published Specification, Figure 12, Paragraphs 10, 35, 47-48, 100 and 130. Polypeptides suspected of being group 2/3 allergens can be assayed for β -expansin activity using techniques routinely employed by one skilled in the art, including cell wall extension and stress relaxation assays provided in the published specification at paragraphs 115 and 133-134.

Because a person of ordinary skill in the art in the fields of molecular biology and biochemistry can easily determine the structural and functional elements of the claims, the claim scope is clearly defined as required under *In re Wands*. The Specification provides a "precise definition, such as by structure, formula ... of the claimed subject matter sufficient to distinguish it from other materials." *Univ. of California v Elli Lilly and Co.*, 43 USPQ 2d 1398 (Fed. Cir. 1997). The Examples in the specification show that one skilled in the art could follow the teachings of the Specification to achieve the desired results, identifying group 2/3 allergens having β -expansin activity.

In light of the above, Applicants respectfully submit that this rejection is not applicable to additional claims 30-37.

B. Written Description

Claims 13-21 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 13 and 14 allegedly encompass any

group 2/3 grass pollen allergen having expansin activity and claims 15-21 allegedly encompass any group 2/3 allergen having expansin activity and the ability to enhance the wall-loosening activity of a β -expansin in plant wall extension and stress relaxation activity. The Examiner writes that all these claims described above encompass a large number of unknown structures whose function has not been described in the specification. The Examiner writes the specification describes just one structure of Lol p3 cDNA encoding a polypeptide as defined in SEQ ID NO:2 and further establishes its function in enhancing the wall-loosening activity of β -expansin in plant wall extension and stress relaxation activity. The Examiner writes, however, a group 2/3 allergen defined in SEQ ID NO:2 does not represent the broadly claimed genus as encompassed by these claims.

Applicants respectfully disagree. The Examiner suggests that additional working examples are required to provide an adequate written description of the claimed genus of the sequences. This is not supported in the Guidelines for Examination of Patent Applications under 35 U.S.C. §112, first paragraph, "Written Description," 66 Fed. Reg. 1099 (published January 5, 2001). The Guidelines provide that an Applicant may also show that an invention is complete by the disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.

The claims of the present application meet the requirements set forth by the Guidelines. As described above, the specification provides guidance regarding detailed, relevant identifying characteristics of group 2/3 allergens. Applicants describe that group 2/3 allergens, unlike expansins, lack the structural domain of domain 1. In addition, Applicants describe multiple assays that can be used to determine if a suspected allergen has β -expansin activity so that one skilled in the art would be able to identify a polypeptide as a group 2/3 allergen. Thus, contrary to the Examiner's statement, one skilled in the art would recognize from the disclosure that Applicants invented and had possession of the claimed subject matter. Applicants respectfully submit that this rejection is not applicable to additional claims 30-37.

VI. Claim Rejections - 35 U.S.C. § 102

Claims 6, 7 and 13-21 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ansari et al. and evidenced by Marino et al.

The Examiner writes that Ansari et al. teach Rye Grass pollen allergen (a group 2/3 allergen) encoding a polypeptide which has 100% amino acid sequence to instant SEQ ID NO:2, wherein N-terminal amino acid sequence of said polypeptide has sequence identity to instant SEQ ID NO:15. The Examiner writes that this is further evidenced by Marino et al. who teach the solution structure of Phl p2 (a group 2/3 allergen) comprising at least more than one aromatic amino acid residue on the protein surface of said allergen.

Applicants respectfully traverse this rejection as applied to new claims 30-37. As an initial matter, Applicants have canceled claims 6-7 and 13-21. New claims 30-37 are directed to a protein preparation useful for the expansion of a plant cell wall comprising a group 2/3 pollen allergen having β -expansin activity. Support for these amendments can be found throughout the

specification as filed but particularly in original claims 6-7 and 13-21 and at page 35 lines 24-25 in the application as filed.

Nowhere in Ansari or Marino is there a teaching or suggestion that the group 2/3 allergens have β -expansin activity, or that a preparation of the protein (group 2/3 allergen) can be useful in expanding a plant's cell wall as now claimed. Accordingly, Ansari et al and Marino et al. fail to teach each and every element of the additional claims and do not anticipate the invention. Applicants respectfully submit that this rejection is not applicable to additional claims 30-37.

VII. New claims

New claims 30-37 have been added to more fully claim the scope of the Applicants' invention. Support for these additional claims can be found in the original claims 6-7, 13-21 as filed and at page 35 lines 24-25 of the specification as filed.

VIII. Conclusion

Please consider this a two-month extension of time from July 4, 2006 to September 4, 2006 and charge Deposit Account No. 26-0084 the amount of \$225.00 for this extension. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi S. Nebel". The signature is fluid and cursive, with the first name being the most prominent.

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